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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,526	06/24/2003	William R. Noyes	3222.01US02	1769

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/602,526	NOYES, WILLIAM R.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 May 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-61* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Humera N. Sheikh
HUMERA N. SHEIKH
PATENT EXAMINER
TC-1600

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Claims 1-61 are pending in this action. Claims 1-61 are subject to an Election/Restriction requirement.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10 & 14-16, drawn to a medical device comprising a biocompatible, biodegradable filler material, classified in class 424, subclass 9.4.

II. Claims 1-8, 11, 12 & 14-16, drawn to a medical device comprising a biocompatible, biodegradable filler material, classified in class 424, subclass 422.

II. Claims 1-9, 13-16 & 39-61, drawn to a medical device comprising a biocompatible, biodegradable filler material and a kit comprising a filler, classified in class 424, subclass 426.

IV. Claims 17-38, drawn to a method comprising introducing a filler to between a first tissue location and a second tissue location, classified in class 424, subclass 9.1.

Note: For restriction purposes, it is assumed that claim 55 refers to the 'kit' of claim 39, rather than the 'method' of claim 39 as currently recited. Claim 55 has been included with Group III kit claims.

Claims 33 & 35 link(s) inventions of Groups I, III and IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 33 & 35. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

The claims of Group I and II are distinct, each from the other. The claims of Group I (1-10 & 14-16) are drawn to a medical device comprising a biocompatible, biodegradable filler material. The claims of Group II (1-8, 11, 12 & 14-16) are drawn to a medical device comprising a biocompatible, biodegradable filler material. The claims of Group I require a radio opaque marker, whereas the claims of Group II require at least one therapeutic agent. The claims of Group I, which require a radio opaque marker are capable of supporting a separate patent within the art. Therefore, the different Groups I and II have different issues regarding patentability. Art anticipating Group I would not necessarily anticipate or even render obvious Group II. The different devices require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. This creates an undue search burden upon the Examiner.

The claims of Group I and III are distinct, each from the other. The claims of Group I (1-10 & 14-16) are drawn to a medical device comprising a biocompatible, biodegradable filler material. The claims of Group III (1-9, 13-16 & 39-61) are drawn to a medical device comprising a biocompatible, biodegradable filler material and a kit comprising a filler. The claims of Group I require a radio opaque marker, whereas the claims of Group III require an osmotic agent. The claims of Group I, which require a radio opaque marker are capable of supporting a separate patent within the art. Therefore, the different Groups I and III have different issues regarding patentability. Art anticipating Group I would not necessarily anticipate or even render obvious Group III. The different devices require completely different searches in

both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. This creates an undue search burden upon the Examiner.

The claims of Group I and IV are distinct, each from the other. The claims of Group I (1-10 & 14-16) are drawn to a medical device comprising a biocompatible, biodegradable filler material. The claims of Group IV (17-38) are drawn to a method comprising introducing a filler to between a first tissue location and a second tissue location. The claims of Group I recite a device that requires a radio opaque marker, whereas the claims of Group IV are drawn to process claims. The claims of Group I, which require a radio opaque marker are capable of supporting a separate patent within the art. Therefore, the different Groups I and IV have different issues regarding patentability. Art anticipating Group I would not necessarily anticipate or even render obvious Group IV. The different devices and methods require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. This creates an undue search burden upon the Examiner.

The claims of Group II and I are distinct, each from the other. The claims of Group II (1-8, 11, 12 & 14-16) are drawn to a medical device comprising a biocompatible, biodegradable filler material. The claims of Group I (1-10 & 14-16) are drawn to a medical device comprising a biocompatible, biodegradable filler material. The claims of Group I require a radio opaque marker, whereas the claims of Group II require at least one therapeutic agent. The claims of Group I, which require a radio opaque marker are capable of supporting a separate patent within the art. Therefore, the different Groups I and II have different issues regarding patentability. Art anticipating Group II would not necessarily anticipate or even render obvious Group I. The

different devices require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. This creates an undue search burden upon the Examiner.

The claims of Group II and III are distinct, each from the other. The claims of Group II (1-8, 11, 12 & 14-16) are drawn to a medical device comprising a biocompatible, biodegradable filler material. The claims of Group III (1-9, 13-16 & 39-61) are drawn to a medical device comprising a biocompatible, biodegradable filler material and a kit comprising a filler. The claims of Group II require at least one therapeutic agent, whereas the claims of Group III require an osmotic agent. Therefore, the different Groups II and III have different issues regarding patentability. Art anticipating Group II would not necessarily anticipate or even render obvious Group III. The different devices require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. This creates an undue search burden upon the Examiner.

The claims of Group II and IV are distinct, each from the other. The claims of Group II (1-8, 11, 12 & 14-16) are drawn to a medical device comprising a biocompatible, biodegradable filler material. The claims of Group IV (17-38) are drawn to a method comprising introducing a filler to between a first tissue location and a second tissue location. The claims of Group II recite a device that requires at least one therapeutic agent, whereas the claims of Group IV are drawn to process claims. Therefore, the different Groups II and IV have different issues regarding patentability. Art anticipating Group II would not necessarily anticipate or even render obvious Group IV. The different device and process require completely different searches in both the

patent and non-patent databases, and there is no expectation that the searches would be coextensive. This creates an undue search burden upon the Examiner.

Similarly, for reasons advanced above, the claims of Group III are distinct from each of Groups I, II and IV.

Similarly, for reasons advanced above, the claims of Group IV are distinct from each of Groups I, II and III.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election of Species:

Note: If Applicant chooses to elect Group IV (claims 17-38), then the following Election of Species for Filler (claim 21) is also required:

Election of Filler:

(a) alginate

(b) gelatin

(c) fibrin, fibrinogen

(d) albumin

(e) polylactide, polyglycolide

(f) polycaprolactone

(g) poly(alpha-hydroxy acid)

(h) polyethylene glycol

(i) thixotropic polymers

(j) thermoreversible polymers

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143). Because the above restriction/election is complex, a telephone call to applicants to request an oral election was not made. See MPEP 812.01

Applicant is also reminded that a 1-month (not less than 30 days) shortened statutory period will be set for response when a written restriction is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Patent Examiner

Art Unit 1615

June 21, 2006

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